



Customer No. 35743

Attorney Docket No. 57361-01041

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Pollak et al. Confirmation No. 8318
Serial No. : 09/913,401
Filed : January 16, 2002
For : **IMMOBILIZED LABELING COMPOUNDS AND METHODS**
Art Unit : 1616
Examiner : Jones, Dameron L.

DECLARATION OF KAREN E. LINDER, PH.D.

I, Karen E. Linder, Ph.D., declare as follows:

1. I am a citizen of the United States of America, and currently reside in Kingston, New Jersey.
2. I received a Bachelor of Science degree in Teaching/Biology in 1976 and a Master of Science degree in Medicinal Chemistry in 1982, both from Northeastern University, Boston, Massachusetts. I received a Ph.D. in Inorganic Chemistry in 1986 from the Massachusetts Institute of Technology, Cambridge, Massachusetts.
3. For over twenty years, I have been engaged in the research and development of diagnostic imaging agents, including labeling compounds and methods. Since 1994, I have been, and currently am, employed by Bracco Research USA, 305 College Road East, Princeton, New Jersey ("Bracco Research") as a research scientist with duties relating to research and development of diagnostic imaging agents, including labeling compounds and methods.

4. I am also an inventor and/or co-inventor of numerous patents owned by Bracco, including various United States, European, and other patents worldwide relating to constructs for diagnostic imaging and therapy, and methods of making the same.

5. I have reviewed the above referenced U.S.S.N. 09/913,401, and am familiar with the subject matter disclosed and claimed therein.

6. I have reviewed the Office Action mailed December 28, 2004 ("Office Action"), and make this declaration in support of the concurrently filed *Amendment and Response To Office Action*.

A. Written Description

7. I understand that in the Office Action, claims 26, 27 and 33 were rejected for failing to comply with the written description requirement of 35 U.S.C. § 112, ¶ 1 based on the terms "disease, disorder or abnormal physical state."

8. I have been informed by the attorneys for U.S.S.N. 09/913,401 ("Applicants' attorneys") that the written description requirement of 35 U.S.C. § 112, ¶ 1 requires that the Specification "describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention."

9. I have further been informed by Applicants' attorneys that one skilled in the art would be an individual with an undergraduate degree in chemistry or biochemistry and at least two years of graduate or postdoctoral work or work experience in the field of radiodiagnostic or radiotherapeutic applications.

10. Therefore, it is my opinion that claims 26, 27 and 33 fully comply with the written description requirement of 35 U.S.C. § 112, ¶ 1 because the terms "disease, disorder or abnormal physical state" are described throughout the disclosure, including, *e.g.*, in the following:

“The invention includes a method of detecting the presence or assessing the severity of a **disease, disorder or abnormal physical state** in a mammal comprising: (a) administering an agent or composition of the invention and (b) detecting the presence or assessing the severity of the **disease, disorder or abnormal physical state**. The presence or severity of the **disease, disorder or abnormal physical state** is detected or assessed with a technique selected from the group consisting of positron emission tomography, nuclear magnetic resonance imaging, scintigraphy, single photon emission computed tomography, perfusion contrast echocardiography, ultrafast X-ray computed tomography, and digital subtraction angiography.”

(Specification, p. 15, line 26 to p. 16, line 5; emphasis added). The phrase, “oncological, neurological, inflammatory, infectious, and degenerative diseases” also finds support throughout the present Specification, for example, in the following:

“The pharmaceutical compositions are used to treat diseases and provide images in **diseases, disorders or abnormal physical states including oncological, neurological, inflammatory, infection, and degenerative diseases**. Other **diseases, disorders and abnormal physical states** will be apparent to those skilled in the art and/or on review of this application or references cited in this application.”

(Specification, p. 16, lines 17-20; emphasis added).

11. The present invention is directed to compositions and methods for generating complex-forming metal ion labeled agents that can be used for diagnosis or therapy in many applications, and has many potential applications. It would be readily understood by those of ordinary skill in the art that the specific diseases, disorders or abnormal physical states to be diagnosed or treated can be ascertained by the nature of the complex that is formed, in particular the targeting molecule element of the claimed compositions.

12. Therefore, one skilled in the art can reasonably conclude, based on the present disclosure which discloses the invention in sufficient detail, that the inventors of U.S. Application Serial No. 09/913,401 had possession of the presently claimed invention as it relates to a method of detecting the presence or assessing the severity of an oncological, neurological,

inflammatory, infectious, and degenerative disease, disorder or abnormal physical state in a mammal, as recited in claims 26 and 33.

13. Similarly, one skilled in the art can reasonably conclude, based on the present disclosure which discloses the invention in sufficient detail, that the inventors of U.S. Application Serial No. 09/913,401 had possession of the presently claimed invention as it relates to a method of radiotherapy of a disease, disorder or abnormal physical state in a mammal, as recited in claim 27.

B. Definiteness

14. I also understand that in the Office Action, claims 26, 27 and 33 were rejected as failing to comply with the definiteness requirement of 35 U.S.C. § 112, ¶ 2 based on the terms “disease, disorder or abnormal physical state.”

15. I have been informed by Applicants’ attorneys that the definiteness requirement of 35 U.S.C. § 112, ¶ 2 requires that the claims “particularly point out and distinctly define the subject matter which Applicants regard as their invention.” In other words, I am informed that the requirements of 35 U.S.C. § 112, ¶ 2 are met if: (a) the claims set forth the subject matter that Applicants regard as their invention; and (b) the claims particularly point out and distinctly define the metes and bounds of the subject matter that will be protected by the patent grant. MPEP § 2171.

16. The present invention is directed to compositions and methods for generating complex-forming metal ion labeled agents that can be used for diagnosis or therapy in many applications, and has many potential applications. It would be readily understood by those of ordinary skill in the art that the specific diseases, disorders or abnormal physical states to be diagnosed or treated can be ascertained by the nature of the complex that is formed, in particular the targeting molecule element of the claimed compositions.

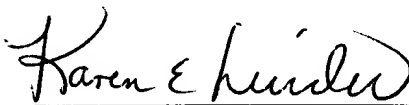
17. Contrary to what was stated in the Office Action, one skilled in the art would be able to ascertain the meaning of the terms, "disease, disorder or abnormal physical state" and "oncological, neurological, inflammatory, infectious, and degenerative disease, disorder or abnormal physical state" as recited, after reviewing the suggested areas of the Specification. These terms are not ambiguous, but are rather very unambiguous.

18. Therefore, for at least the above reasons, the terms "disease, disorder or abnormal physical state" are definite because a skilled artisan would know that they do indeed "particularly point out and distinctly define the subject matter which Applicants regard as their invention." In other words, claims 26, 27 and 33 do set forth the subject matter that Applicants regard as their invention, and do particularly point out and distinctly define the metes and bounds of the subject matter that will be protected by the patent grant.

I HEREBY DECLARE that all statements made of my own knowledge are true, and all statements made on information and belief are believed to be true. I make this declaration understanding that willful false statements and the like are punishable by fine or imprisonment, or both (18 U.S.C. § 1001) and may jeopardize the validity of the application or any patent issuing thereon.

Dated: April 26, 2005

Respectfully submitted,

By: 

Karen E. Linder, Ph.D.